

REMARKS

In response to the January 17, 2006 Office Action, the listing of claims has been modified to comply with the requirements of 37 C.F.R. § 1.121. Claims 54-56, 63 and 65 have now been listed as “previously presented.” The following remarks are those filed in the Amendment dated October 27, 2005.

A request for continued examination under 37 C.F.R. 1.114 has been entered. The Examiner’s Office Action of April 27, 2005 has been received and carefully considered. Reconsideration of this application in light of the amendment and the allowance of this application are respectfully requested.

Prior to the Office Action, claims 50-56 and 58-66 were pending. Claims 54-56, 63 and 65 were allowed in the Office Action of April 27, 2005. In response to the Office Action, claims 51-53, 58, 60 and 62 are amended, claims 50, 59, 64 and 66 are cancelled and new claims 67-80 are added. New claims 67-80 are fully supported by the specification and no new matter has been added. Accordingly, upon entry of this amendment, claims 51-53, 58, 60-62, and 67-80 remain pending in the application, of which claim 67 is independent. In view of the remarks below, Applicants respectfully request reconsideration of this application.

Referring now to the Office Action, the Applicants acknowledge with appreciation, the Examiner’s allowance of claims 54-56, 63 and 65.

Claims 50-53, 58, and 59, 64 and 66 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kremer, (US 4,635,488). The Examiner’s remarks regarding this rejection are found on pages 2-3 of the non-final Office Action. Applicants respectfully traverse this rejection.

As indicated above claim 50 has been cancelled. New independent claim 67 now recites a device for assay of antibodies in oral fluids, comprising a housing and a strip, the strip comprising a collection strip for collecting an oral fluid sample in fluid communication with a lateral flow assay strip, wherein the lateral flow assay strip is contained substantially within the housing, contains at least one blocking agent or at least one buffer to adjust pH of the oral fluid sample, contains at least one reagent used to detect the presence or absence of

at least one type of antibody in the oral fluid sample, and contains one or more zones that indicate the presence or absence of the type of antibody in the oral fluid sample.

Kremer does not teach or suggest such a device. Kremer is directed to a body fluid sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in that open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the end of the tube for contact with a fluid to be collected. (Kremer, col. 2, ll. 50-55) Nor would the teachings of Kremer have rendered such a device obvious to one of ordinary skill in the art.

Claim 51-53 and 58 are dependent on claim 67 and the Examiner's rejection is believed to be rendered moot in view of the above remarks to the independent claim. Claims 59, 64 and 66 are cancelled.

In view of the above, the applicants respectfully contend that the Examiner's rejection based on Kremer is improper, and should be withdrawn. Correspondingly, the allowance of independent claim 67 is respectfully requested.

Claims 60-62 are rejected under 35 U.S.C. § 103(a) over Kremer (US 4,635,488) in view of Ullman (US 4,624,929). The Examiner cites Ullman for its teaching of assay components including an immunospecific binding partner with a detectable label, enzyme labeled binding partners antigens and antibodies. The examiner further asserts that it would have been obvious to one of ordinary skill in the art to have used the assay chemistry of Ullman ('929) in the device of Kremer ('488), because the invention of Kremer concerns the structure of the device and one would look to the prior art for the chemical aspects of the assay, especially to Ullman because both Ullman and Kremer concerns testing saliva. Applicants respectfully traverse this rejection.

As discussed above, as Kremer does not teach or suggest Applicants' claimed device, the Examiner's rejection is believed to be rendered moot in view of the above remarks. In this regard, it is noted that Ullman reference fails to cure the deficiencies of the primary Kremer reference so that, even if these references are combined in the manner suggested by the Examiner, they still fail to disclose, teach, or otherwise suggest Applicants' invention as claimed. Nonetheless, the Applicants respectfully contend that Ullman fails to teach, disclose or suggest the chemical aspects of the assay as claimed in Applicants' invention.

Ullman discloses a device collecting a predetermined amount liquid sample and the dilutes the liquid sample by virtue of the device being adapted for use with a container having a certain volume of the diluting liquid. The Ullman device uses pressure to move the diluted sample from the container into a housing which may contain an assay strip (40). See Ullman Figs. 4 and 5. Ullman's device may also contain a means (28) for removing excess liquid and filtering out particles.

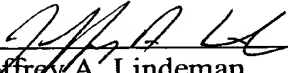
Ullman fails to disclose, teach, or otherwise suggest a device of assay of antibodies in oral fluids as specifically recited in independent claim 67. One of ordinary skill would not have found Applicants' claimed device obvious from Ullman, alone or in combination with Kremer. Applicants respectfully request this rejection be withdrawn.

Finally, the new claims 68-80 have been added are all dependent claims, each of which ultimately depend on independent claim 67 which is believed to be allowable. Correspondingly, the entry and the allowance of these new claims are also respectfully requested. In this regard, no new matter has been added by the above amendments to the claims.

In view of the foregoing, Applicants respectfully request reconsideration of this application. While this application is now believed to be in condition for allowance, should the Examiner find some issue to remain unresolved, or should any new issues arise which could be eliminated through discussions with Applicants' representative, then the Examiner is invited to contact the undersigned by telephone in order that the further prosecution of this application can thereby be expedited.

Applicants do not believe that any fees are due with the filing of this response. If there are any fees due in connection with this response, please charge those fees to Deposit Account No. 19-2380.

Respectfully submitted,
NIXON PEABODY, LLP



Jeffrey A. Lindeman
Reg. No. 34,658

Dated: **February 1, 2006**

Customer No. 22204
Nixon Peabody LLP
901 9th Street, N.W., Suite 900
Washington, D.C. 20004
Tel: 202-585-8350